510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:

B. Analyte: Control materials for:

Acetaminophen, Amikacin, Amitriptyline, Caffeine, Carbamazepine, Chloramphenicol, Cocaine, Cyclosporine, Desipramine, Digoxin, Disopyramide, Estriol, Ethanol, Ethosuximide, Gentamicin, Imipramine, Lidocaine, Lithium, Methotrexate, N-Acetylprocainamide, Netilmicin, Nortryptylinr, Phenobarbital, Phenytoin, Primidone, Procainamide, Quinidine, Salicylate, Theophylline, Tobramycin, Total T3-Triidothyronine, Total T4, Tricyclic Antidepressants, TSH, Valporic Acid, and Vancomycin.

C. Type of Test:
NA

D. Applicant:

Medical Analysis Systems Inc.

E. Proprietary and Established Names:

MAS PAR TDM Liquid Assayed Therapeutic Drug Control

F. Regulatory Information:

1. Regulation section:
   21 CFR § 862.3280, Clinical toxicology control material
2. Classification:
   Class I
3. Product Code:
   DIF
4. Panel:
   Toxicology (91)

G. Intended Use:

1. Intended Use(s):
   Refer to the Indications for Use.

2. Indication(s) for use:

The MAS PAR TDM is intended for use as a consistent test sample of known concentration for monitoring assay conditions in many clinical determinations. Include PAR TDM with patient serum specimens when assaying for any of the listed constituents. Assay values are provided for the specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.

3. Special condition for use statement(s): None

4. Special instrument requirements: None

H. Device Description:

The MAS PAR TDM is prepared from a bovine serum base. Analyte levels are adjusted with various drugs, drug metabolites and purified chemicals. Preservatives and stabilizers are added to maintain product integrity. The product will sold in separate kits of Level 1, Level 2, and Level 3 as well as a sample pack containing one vial each of all three levels.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   MAS PARTDM
2. Predicate K number(s):
   K936166
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Intended Use	The MAS PAR TDM is intended for use as a consistent test sample of known concentration for monitoring assay conditions in many clinical determinations. Include PAR TDM with patient serum specimens when assaying for any of the listed constituents. Assay values are provided for the specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.	The MAS PAR TDM is intended for use as a consistent test sample of known concentration for monitoring assay conditions in many clinical determinations. Include PAR TDM with patient serum specimens when assaying for any of the listed constituents. Assay values are provided for the specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.
Product state at purchase	Liquid	Liquid
Levels available	Three	Three

Differences		
Item	**Device**	**Predicate**
Shelf life	36 months	24 months

J. Standard/Guidance Document Referenced (if applicable):
None referenced

K. Test Principle:
NA

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. Precision/Reproducibility: NA

   b. Linearity/assay reportable range: NA

   c. Traceability (controls, calibrators, or method):

All values directly assayed have been assigned with instrument and instrument manufacturer's reagents available at the time of assay. Subsequent instrument or reagent modifications may invalidate these assigned values.

d. Detection limit: NA

e. Analytical specificity: NA

f. Assay cut-off: NA

2. Comparison studies:
   a. Method comparison with predicate device: NA

   b. Matrix comparison: NA

3. Clinical studies:
   a. Clinical sensitivity: NA

   b. Clinical specificity: NA

   c. Other clinical supportive data (when a and b are not applicable): NA

4. Clinical cut-off: NA
   .
5. Expected values/Reference range:

Expected values may vary slightly with different reagent and/or methodologies used. Refer to the table included in package insert for values obtained for specific systems. Values listed are specific for this lot of control only. Good laboratory practice suggests that each laboratory establish its own parameters.

M. Conclusion:

I recommend that the MAS PAR TDM Liquid Assayed Therapeutic Drug Control is substantially equivalent to the legally marketed predicate device.